NOV 2 4 2000

K002184

Summary of Safety and Effectiveness
for
COD Compression Osteotomy Device

This safety and effectiveness summary for the COD Compression Osteotomy Device is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

Walter Abendschein, M.D.
1818 Tottenham Court
Reston, VA 20194-1415

Contact Person :

Walter Abendschein, M.D.
5530 Wisconsin Avenue, Suite 705
Chevy Chase, Md. 20815
Telephone: (301) 656-4317

Date Prepared: July 19, 2000

2. Tradename: COD Compression Osteotomy Device
Common Name: Osteotomy System
Classification Name: Single/ multiple component metallic bone fixation appliances and accessories (888.3030)

3. Predicate or legally marketed devices which are substantially equivalent:

- NexGen Osteotomy System (Zimmer)
- Richards High Tibial Osteotomy System (S &N Richards)
- First Step Osteotomy System (Howmedica)
- Natural Knee HTO System (Sulzer Intermedics)

4. Description of the device :

The COD Compression Osteotomy Device is an assembled device used to perform closing wedge osteotomies. It consists of adjustable plate assemblies, and cortical and cancellous bone screws in various sizes.

Materials: The devices are manufactured from 316 LVM stainless steel or Ti 6Al-4V ELI alloy per ASTM standards.

Function: The system functions to provide immediate stability and temporary fixation during the natural healing process following osteotomies.

5. Intended Use:

The COD Compression Osteotomy Device is indicated for use in tibial osteotomies. Tibial osteotomy is generally indicated in young, active patients with painful unicompartmental osteo-arthritis associated with varus deformity of no more than 11 degrees.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the COD Compression Osteotomy Device and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Walter Abendschein, M.D.
5530 Wisconsin Avenue, Suite 705
Chevy Chase, Maryland 20815

Re: K002184
Trade Name: COD Compression Osteotomy Device
Regulatory Class: II
Product Code: HRS
Dated: September 20, 2000
Received: September 22, 2000

Dear Dr. Abendschein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K002184

Device Name : COD Compression Osteotomy Device

Indications For Use :

The COD Compression Osteotomy Device is indicated for use in tibial osteotomies. Tibial osteotomy is generally indicated in young, active patients with painful unicompartmental osteo-arthritis associated with varus deformity of no more than 11 degrees

PLEASE DO NOT WRITE BELOW TH IS LINE - CONTINUE ON ANOTHE PAGE IF NEEDED)

Concurrence of CDRH, Office f Device Evaluation (ODE)

Prescription use X
(PER 21 CFR 801.109)

OR

Over-the-counte se

(optional forma 2-96)

for Mark N Milkerson

(Division Sign-Off)
Division of General Restor Devices
510(k) Number K002184